

REMARKS

Applicant thanks Examiner Navarro for the telephonic Interview on March 10, 2005. By the present communication, claims 17, 18, 60, 63 and 67 have been canceled without prejudice, preserving Applicant's right to pursue the canceled subject matter in a continuing application. Claims 1, 3, 5-10, 19, 21, 33, 34, 39, 62, 64, 68 and 69 have been amended as set forth in the above "Listing of the Claims," and new claims 71-74 have been added. Support for the terms "having about 11 to 20 amino acid residues" and "at least 9 amino acid residues" may be found, among others, in Table 1 at page 12 of the specification as filed, wherein disclosure of core epitopes having 9 amino acid residues and at least one sequence being flanked by at least one amino acid is provided.

The amended and new claims are thus supported by the specification and the original claims, and do not add new matter. The amendments have been made to address particularly preferred aspects and embodiments of the invention, not for reasons of patentability. As such, Applicants expressly reserve the right to pursue claims directed to subject matter no longer or not yet pending in a related application. Thus, upon entry of the amendments, claims 1-16, 19-24, 33-34, 38-42, 61, 62, 64-66, 68, 69 and 71-74 will be pending.

Rejection Under 35 U.S.C. § 102

A. Applicant respectfully traverses the rejection of claims 1-19, 21, 24, 33-39, 60-62, and 64-66 under 35 U.S.C. 102(b) as allegedly being anticipated by Anderton et al. (hereinafter "Anderton"). Applicants have canceled claims 17 and 18 without prejudice, rendering the rejection moot as pertains to claims 17 and 18. The Examiner maintains that Anderton discloses "peptide fragments which are useful for protection against or treatment of an inflammatory disease, including autoimmune diseases, such as diabetes, arthritic diseases, arteriosclerosis, multiple sclerosis, myasthenia gravis, or inflammatory responses due to tumor or transplant rejection." (office Action, page 3). The Examiner further states that Anderton discloses a peptide with 100% identity with SEQ ID NO: 21 of the instant application.

As amended, claim 1 distinguishes from the disclosure of Anderton by requiring an isolated peptide having about 11 to 20 amino acid residues wherein at least 9 amino acid residues of the peptide consist of a sequence as set forth in SEQ ID NO: 18, SEQ ID NO: 20, or SEQ ID NO: 23. Anticipation under 35 U.S.C. § 102(b) requires that the reference recite each and every element of the claims in a single document. Since Anderton et al. now fail to disclose each and every element of the invention methods, as defined by amended claim 1, Applicants respectfully submit that the Examiner has failed to establish anticipation under 35 U.S.C. § 102(b) over Anderton et al. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Applicant respectfully traverses the rejection of claims 67 and 69 under 35 U.S.C. 102(b) as allegedly being anticipated by Van Eden et al. (hereinafter "Van Eden"). The Examiner alleges that Van Eden discloses "polypeptide compositions which *comprise* a sequence with 100% identity to SEQ ID NO:6 of the instant invention." (Office action, page 7, emphasis added). However, as indicated by the Examiner, "claims 68 and 70 are objected to for depending upon a rejected base claim, however claims 68 and 70 are free of the prior art of record." (Office Action, page 7). Thus, to further prosecution, Applicants have canceled claim 67 and amended claim 69 to indicate that the peptide and composition of claims 68 and 69 should *consist of* SEQ ID NO: 6.

Anticipation under 35 U.S.C. § 102(b) requires that the reference recite each and every element of the claims in a single document. Since Van Eden et al. now fail to disclose each and every element of the invention methods, as defined by amended claims 68 and 69, Applicants respectfully submit that the Examiner has failed to establish anticipation under 35 U.S.C. § 102(b) over Van Eden et al. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested

Rejection Under 35 U.S.C. § 103

Applicant respectfully traverses the rejection of claims 1-24, 33-34, 38-42, and 60-66 under 35 U.S.C. §103(a) as allegedly unpatentable over Anderton, in view of Srivastava, Russel-Jones, *et al.*, and Guichard, *et al.* Applicants have canceled claims 17 and 18 without prejudice, rendering the rejection moot as pertains to claims 17 and 18. The burden of proof in establishing a *prima facie* case of obviousness under § 103 clearly rests with the Patent Office. *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). In establishing a *prima facie* case, the Patent Office, among other things, must show that (1) the prior art would have suggested to those of ordinary skill in the art that they should make the claimed invention and (2) that the prior art would have revealed a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). “Both the suggestion and the reasonable expectation of success must be found in the prior art, not in the applicant’s disclosure.” *Id.* Thus, “particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.” *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). Further, when relying on the knowledge of persons of ordinary skill in the art, the Patent Office must “explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination.” *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). “The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with.” *In re Sang Su Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002) (citations omitted).

To date, the Patent Office has failed to provide objective evidence of any suggestion or motivation in the prior art to combine and modify the particular references cited by the Office. Instead, the Office has simply recited elements gleaned from the various references and stated that the combination of these elements would have been obvious to one skilled in the art. It is well settled that the Patent and Trademark Office cannot pick and choose among the individual elements of assorted prior art references to recreate the claimed invention. *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 887 (Fed. Cir. 1988). In addition,

it is now well established that “[b]road conclusory statements regarding the teaching of multiple references standing alone are not ‘evidence’.” *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999); see also *In re Kotzab*, 217 F.3d at 1370. “Th[e] factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority.” *In re Sang Su Lee* 277 F.3d at 1343-44. Without such objective evidence to combine the references, it is inferred that the references were selected with the assistance of hindsight. *In re Rouffet*, 149 F.3d at 1358. It is well-established that the use of hindsight in the selection of references that comprise a case of obviousness is forbidden. *Id.*

Applicants’ remarks above regarding the failure of Anderton to disclose the invention peptides of the present invention apply equally and are incorporated here. The Examiner relies upon Srivastava for disclosure of stress protein-peptide complexes containing a therapeutically effective amount of a cytokine including IL-1, IL-2 etc. The Examiner relies upon Russel-Jones for disclosure of covalent attachment of BSA to a peptide antigen resulting in a significant enhancement of the immune response. Finally, the Examiner relies upon Guichard for disclosure of use of D amino acids to replace natural L-peptides, resulting in peptides with a higher metabolic stability since most natural proteases cannot cleave D-amino acid residues.

Applicants submit that the combination of Anderton, Srivastava, Russel-Jones, and Guichard, does not teach or suggest all of the elements of the subject matter claimed. There is no teaching nor any suggestion in any of the cited references to modify the teachings of Anderton to arrive at an isolated peptide having about 11 to 20 amino acid residues wherein at least 9 amino acid residues of the peptide consist of a sequence as set forth in SEQ ID NO: 18, SEQ ID NO: 20, or SEQ ID NO: 23. Accordingly, Applicants submit that amended claims 1-16, 19-24, 33-34, 38-42 and 60-66 are not *prima facie* obvious over the combined teachings of Anderton, *et al.*, Srivastava, Russel-Jones, *et al.*, and Guichard, *et al.*, and withdrawal of the rejection is respectfully requested.

In re Application of:
Albani and Prakken
Application No.: 09/828,574
Filed: April 6, 2001
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PATENT
Attorney Docket No.: UCSD1310-1

CONCLUSION

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect respectfully is requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

Enclosed is Check No. 575920 totaling \$1,235.00 to cover Request for Continued Examination (\$395.00), The One-Month extension of time fee (\$60.00) and excess and multiple claim fee (\$780.00). The Commissioner is hereby authorized to charge any other fees that may be associated with this communication, or credit any overpayment to Deposit Account No. 07-1896.

Respectfully submitted,

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